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IPE JC68 FEB 0 5 2001 PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

PODSAKOFF et al.

Serial No.: 09/755,734 Group Art Unit: Unassigned

Filing Date: January 4, 2001 Examiner: Unassigned

Title: METHODS FOR DELIVERING DNA TO MUSCLE CELLS USING RECOMBINANT ADENO-ASSOCIATED VIRUS VECTORS

TRANSMITTAL LETTER

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is an Information Disclosure Statement and a Form PTO-1449. It is believed that no fee is due.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17 and 1.21 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 18-1648.

Respectfully submitted,

Date: 1/31/01

By: [signature]
Roberta L. Robins
Registration No. 33,208

ROBINS & ASSOCIATES
90 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 325-7812
Facsimile: (650) 325-7823

Atty Dkt No. 800-0009.05
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Serial No.: 09/755,734 Group Art Unit: Unassigned

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Title: METHODS FOR DELIVERING DNA TO MUSCLE CELLS USING RECOMBINANT ADENO-ASSOCIATED VIRUS VECTORS

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

The information listed below may be material to the examination of the above-identified application. A completed Form PTO-1449 listing the references identified below accompanies this paper. All references are of record, or have been submitted in related application serial number 09/309,042 from which the present application claims priority under 35 U.S.C. §120. Thus, pursuant to C.F.R. §1.98(d), copies of the references are not included.

Applicants would appreciate the Examiner's initialing and returning the form to indicate that the references have been reviewed and made of record in the present application. The information includes:

- United States Patent No. 5,139,941 issued Aug. 18, 1992, to Muzyczka et al.;
- United States Patent No. 5,173,414 issued Dec. 22, 1992, to Lebrowski et al.;
- United States Patent No. 5,252,479 issued Oct. 12, 1993, to Srivatava;
- United States Patent No. 5,478,745 issued Dec. 26, 1995, to Samulski et al.;

United States Patent No. 5,587,308 issued Dec. 24, 1996, to Carter et al;

United States Patent No. 5,589,362 issued October 31, 1996, to Bujard et al.;

United States Patent No. 5,658,656 issued August 19, 1997, to Billiar et al.;

International Publication No. WO 94/13788, published June 23, 1994;

International Publication No. WO 95/13376, published May 18, 1995;

International Publication No. WO 95/20671, published August 3, 1995;

International Publication No. WO 95/34670, published December 21, 1995;

Acsadi et al., "Human Dystrophin Expression in MDX Mice After Intramuscular Injection of DNA Constructs," Nature 352:815-818 (1995);

Acsadi et al., "Cultured Human Myoblast and Myotubes Show Markedly Different Transducibility by Replication-Defective Adenovirus Recombinants," *Gene Therapy* 1:338-340 (1994);

Acsadi et al., "A Differential Efficiency of Adenovirus-Mediated *in vivo* Gene Transfer Into Skeletal Muscle Cells of Different Maturity," *Hum. Mol. Genetics* 3:579-584 (1994);

Barr and Leiden, "Systemic Delivery of Recombinant Proteins by Genetically Modified Myoblast," *Science* 254:1507-1509 (1991);

Bartlett et al., *Am. J. Human Genetics* 57 Supp. 4 #A235;

Blau et al., "Myoblast in Pattern Formation and Gene Therapy," *Trends in Genetics* 9(9):269 (1993);

Blau and Springer, "Molecular Medicine Muscle-Mediated Gene Therapy," *New Eng. J. Med.* 333:1204-1207 (1995);

Blau and Springer, "Molecular Medicine Muscle-Mediated Gene Therapy," *New Eng. J. Med.* 333:1554-1556 (1995);

Brockstedt et al., *Clin. Immuno.* 82(1):67-75 (1999);

Clark et al., "Cell Lines for the Production Recombinant Adeno-Associated Virus," *Human Gene Therapy* 6:1329-1341 (1995);

Culver et al., *Trends Genetics* 10(5):174-178 (1994);

Dai et al., "Gene Therapy Via Primary Myoblasts: Long-Term Expression of Factor IX Protein Following Transplantation *in vitro*," *Proc. Natl. Acad. Sci.* USA 89:10892-10895 (1992);

Dai et al., "Cellular and Humoral Immune Responses to Adenoviral Vectors Containing Ractor IX Gene: Tolerization of Factor IX and Vector Antigens Allows for Long-Term Expression," *Proc. Natl. Acad. Sci.* USA 92:1401-1405 (1995);

Davis et al., "Direct Gene Transfer Into Skeletal Muscle *in vivo*: Factors Affecting Efficiency of Transfer and Stability of Expression," *Hum. Gene therapy* 4:151-159 (1993);

Descamps et al., "Organoids Direct Systemic Expression of Erythropoietin in Mice," *Gene Therapy* 2:411-417 (1995);

Dhawan et al., "Systemic Delivery of Human Growth Hormone by Injection of Genetically Engineered Myoblast," *Science* 254:1509-1512 (1991);

Einerhand et al., *Gene Therapy* 2(5):336-343 (1995);

Flotte et al., "Gene Expression from Adeno-Associated Virus Vectors in Airway Epithelial Cells, " *Am. J. Respir. Cell Mol. Biol.* 7:349-356 (1992);

Flotte et al., "Expression of the Cystic Fibrosis Transmembrane Conductance Regulator From a Novel Adeno-Associated Virus Promoter," *J. Biol. Chem.* 268:3781-3790 (1993);

Flotte et al., "Stable *in vivo* Expression of the Cystic Fibrosis Transmembrane Conductance Regulator with an Adeno-Associated Virus Vector," *Proc. Natl. Acad. Sci.* USA 90:10613-10617 (1993);

Flotte et al., "Adeno-Associated Virus Vector Gene Expression Occurs in Nondividing Cells in the Absence of Vector DNA Integration," *Am. J. Respir. Cell Mol. Biool.* 11:517-521 (1994);

Gilgenkrantz et al., "Transient Expression of Genes Transferred *in vivo* Into Heart Using First-Generation Adenoviral Vectors: Role of the Immune response," *Hum. Gene Therapy* 6:1265-1274 (1995);

Hamamori et al., "Myoblast Transfer of Human Erythropoietin Gene in a Mouse Model of Renal Failure," *J. Clin. Inves.* 95:1808-1813 (1995);

Hamamori et al., "Persistent Erythropoiesis by Myoblast Transfer of Erythropoietin cDNA," *Human Gene Therapy* 5:1349-1356 (1994);

Herzog et al., *Proc. Natl. Acad. Sci.* 94:5804-5809 (1997);

Hodgson, *Exp. Opin. Ther. Pat.* 5(5):459-462 (1995);

Kaplitt et al., "Long-Term Gene Expression and Phenotypic Correction Using Adeno-Associated Virus Vectors in the Mammalian Brain.," *Nature Genetics.* 8:148-154 (1994);

Kessler et al., "Gene Delivery to Skeletal Muscle Results in Sustained Expression and Systemic Delivery of a Therapeutic Protein," *Proc. Natl. Acad. Sci.* USA 93:14082-14087 (1996);

Knowles et al., "A Controlled Study of Adenoviral-Vector-Mediated Gene Transfer in the Nasal Epithelium of Patients with Cystic Fibrosis," *The New Eng. J. of Med.* 333(13):823-831 (1995);

Kourtis et al., "Cardiac Gene Therapy With Adeno-Associated Virus Suppression," *Modern Pathology* 8(1):33A (1995);

Lafont, *Lancet* 346:1442-1443 (1995);

Leiden, J.M., "Gene Therapy-Promise, Pitfalls and Prognosis," *New Eng. J. Med.* 333:871-872 (1995);

March et al., *Clin. Res.* 40(2):358A (1992);

Marshall et al., *Science*, 269:1050-1055 (1995);

Mendell et al., "Myoblast Transfer in the Treatment of Duchenne's Muscular Dystrophy," *New Eng. J. Med.* 333:832-838 (1995);

Miller et al., *FASE BJ* 9:190-199 (1995);

Naffakh et al., "Sustained Delivery of Erythropoietin in Mice by Genetically Modified Skin Fibroblast," *Proc. Natl. Acad. Sci.* USA 92:3194-3198 (1995);

Naffakh et al., "Long-Term Secretion of Therapeutic Proteins from Genetically Modified Skeletal Muscles," *Human Gene Therapy* 7:11-21 (1996);

Nakai et al., *Blood* 91(12):4600-4607 (1998);

Orkin et al., *Report and Recommendation from the Panel to Assess the NIH Investment...* (1995);

· Osborne et al., "Gene Therapy for Long-Term Expression of Erythropoietin in Rats," *Natl. Acad. Sci.* USA 92:8055-8058 (1995);

· Podsakoff et al., "Efficient Gene Transfer into Nondividing Cells by Adeno-Associated Virus-Based Vectors," *J. Virol.* 68:5656-5666 (1994);

· Podsakoff et al., "AAV Vector-Mediated Gene Delivery to Skeletal Muscle *In Vivo* Results in Sustained Levels of Systemic Erythropoietin," *Gene Therapy Clinic* 88(10):1066 (269A) (1996);

· Podsakoff et al., "Long-Term *In Vivo* Gene Expression in Muscle Using AAV Vectors," *Blood* 86(10):1004A (1995);

· Quantin et al., "Adenovirus as an Expression Vector in Muscle Cells *in vivo*," *Proc. Natl. Acad. Sci.* USA 89:2581-2584 (1992);

· Raz et al., "Systemic Immunological Effects of Cytokine Genes Injected into Skeletal Muscle," *Proc.Natl. Acad. Sci.* USA 90:4523-4527 (1993);

· Restifo et al., *J. Immunotherapy* 14:182-190 (1993);

· Russell et al., "Adeno-Associated Virus Vectors Preferentially Transduce Cells in S phase," *Proc Natl. Acad. Sci.* USA 91:8915-8919 (1994);

· Synder et al., *Nature Gent.* 16:270-276 (1997);

· Tripathy et al., "Stable Delivery of Physiologic Levels of Recombinant Erythropoietin to the Systemic Circulation by Intramuscular Injection of Replication-Defective Adenovirus," *Proc. Natl. Acad. Sci.* USA 91:115;

· Verma et al., *Science* 389:239-242 (1997);

· Villeval et al., "Retrovirus-Medicated Transfer of the Erythropoietin Gene in Hematopoietic Cells Improves the Erythrocyte Phenotype in Murine β-Thalassemia," *Blood* 84(3): 928-933 (1994);

· Watson et al., *Gene Therapy* 5:1642-1649 (1998);

· Wolff et al., "Direct Gene Transfer into Mouse Muscle *in vivo*," *Science* 247:1465-1468 (1990);

· Wolff et al., "Long-Term Persistence of Plasmid DNA and Foreign Gene Expression in Mouse Muscle," *Human Mol. Gent.* 1:363-369 (1992);

- Xioa et al., *J. Virol.* 70(11):8098-8108 (1996); and
- Xioa et al., *Adv. Drug Del. Rev.* 12:201-215 (1993).

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

Respectfully submitted,

Date: 1/31/01 By: _____
Roberta L. Robins
Registration No. 33,208

ROBINS & ASSOCIATES
90 Middlefield Road, Suite 200
Menlo Park, CA 94025
Telephone: (650) 325-7812
Facsimile: (650) 325-7823